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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/739,406	12/18/2000	Weiyu Fan	11936.6USH1	2546

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EXAMINER

LEVY, NEIL S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 08/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/739,406

Applicant(s)

FAN ET AL.

Examiner

Neil Levy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-40 is/are pending in the application.
- 4a) Of the above claim(s) 18-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-12, 32-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 7-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 18-31 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 13.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejections are governed by 37 CFR 1.116; amendments submitted after allowances are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between products claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The rejection under 35 USC first paragraph 112 is withdrawn.

Claims 14, 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. Please spell out abbreviations at first appearance in claims.

Claims 7-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsugita et al – 4983304 in view of Hershberger – 4806474 and Teslenko et al 6333399.

Tsugita clearly indicates chitosan can come from fungus treatment, and can be deacetylated to almost 100%; however, the composition then becomes less desirable if it is used as a membrane (col. 1). However, other uses are known flocculating agent (lines 13-16). The preferential use of crust oceans is not critical; neither is the instant preferential use of fungus. In either case, it is obvious that attainment of a chitosan composition of over 85 to near 100% is known in the art. The various attributes then claimed regarding what happens when chitosan is deployed in acid, the viscosity, turbidity characteristics of the deacytelated chitosan, and with in the purview of one in the art to modify in order to optimize the effects desire. Examples show film advantageous when 9-12% chitosan is used, rather than 2% of comparative Example 2.

Hershberger also provides chitosan, from uniform misdial fungus. *Aspergillum* (example 2) *niger*, also for use as films, flocculants and other (col. 3, top) purposes commonly provided by shellfish chitosan. Preparation is similar to that of the instant invention and art recognized methods, such as Tsugita's, and, as shown by Tsugita, can then be used their to achieve the desired degree of deacytelation; using *aspergillum niger* as a chitin source. Claim 9 of Hershberger indicates solubilization of chitosan is known, by utilizing dilute acid, and thus desired turbidity, viscosity can be obtained. Viscosity shown is less than 25 centipoises at room temperature (Table 1) of a .5%

solution. PH was adjusted with acetic acid (col. 5, lines 15-18). Ash removal would have resulted from the processing.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to utilize chitosan compounds to provide films, flocculants and other compositions to use that Tsugita, modified as desired to substitute fungi sources shown to be advantageous by Hershberger, and useful for the same purposes as shellfish sources. The selection of degree of deacytation is shown as a result effective parameter chosen to obtain desired effects. As is the % chitosan in a composition, again a matter of choice, depending upon and use intended. The viscosity and turbidity then follow as functions of the degree of deacytation and concentration of the chitosan; the former shown by Tsugita and Tesyanko (col. 5, lines 38-45) the latter by Hershberger.

It would be obvious to vary the nature of each ingredient to optimize the effects desired. As taught by Teshenko (col. 4, line 18 – col. 6, line 6).

There is no unusual and/or unexpected results obtained since the prior art is well aware of the degree of deacytation attainable for enhancement and the use of ingredients the functionality for which they are known to be used is not a basis for patentability.

Applicant has not provided any objective evidence of criticality, non-obvious or unexpected results that the administration of the particular ingredients' or concentrations provides any greater or different level of prior art expectation as claimed. All these components are old, art recognized forms.

Claims 7-9, 13-17 and 32, 33, 37-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Teslenko et al 6333399.

See example 1: chitosan from *A. niger* 89% deacytelated is the instant composition. Note that minerals are removed (2.) thus, ash would be less than 0.5%. Other microbes include yeasts and aspergillum species as source material (col. 3, lines 10-20). Various uses are achievable (col. 4, line 28 – line 65, col. 5) as a function of the degree of deacyetylation. The thus attained chitosan, if subjected to the conditions of instant dependent claims, would inherently demonstrate the instant characteristics of turbidity and viscosity.

Applicant's arguments filed on 12/19/03 have been fully considered but they are not persuasive. Applicant's arguments in essence are that the instant invention is not reclaiming that which is known, but that aspect of the use of fungal chitosan deacetylated at over 95%. However, the Tsugita patent does show 100% attainable, albeit not desirable for membranes, and further shows microbial sources to be useful, albeit not preferred. We find no more than preference for the instant fungal sources - no criticality over shellfish. We so see in the cited prior art advantages however for fungal/yeast sources.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is (571) 272-0633. The examiner can normally be reached on Monday to Friday 9 Am 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on (571) 272-0629. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Levy/LR
July 30, 2004

NEIL S. LEVY
PRIMARY EXAMINER